ORIGINAL CONTRIBUTIONS

IMPACT OF THE PRIVACY RULE ON THE STUDY OF OUT-OF-HOSPITAL PEDIATRIC CARDIAC ARREST

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ABSTRACT

Introduction. The Privacy Rule, a follow-up to the Health Insurance Portability and Accountability Act, limits distribution of protected health information. Compliance with the Privacy Rule is particularly challenging for prehospital research, because investigators often seek data from multiple emergency medical services (EMS) and receiving hospitals. **Objective.** To describe the impact of the Privacy Rule on prehospital research and to present strategies to optimize data collection in compliance with the Privacy Rule. **Methods.** The CanAm Pediatric Cardiopulmonary Arrest Study Group has previously conducted a multicentered observational study involving children with out-of-hospital cardiac arrest. In the current study, we used a survey to assess site-specific methods of compliance with the Privacy Rule and the extent to which such strategies were successful. **Results.** The previously conducted observational study included collection of data from a total of 66 EMS agencies (range of 1–37 per site). Data collection from EMS providers was complicated by the lack of a systematic approval mechanism for the research use of EMS records and by incomplete resuscitation records. Agencies approached for approval to release EMS data for study purposes included Department of Health Institutional Review Boards, Fire Commissioners, and Commissioners of Health. The observational study included collection of data from a total of 164 receiving hospitals (range of 1–63 per site). Data collection from receiving hospitals was complicated by the varying requirements of receiving hospitals for the release of patient survival data. **Conclusions.** Obtaining complete EMS and hospital data is challenging but is vital to the conduct of prehospital research. Obtaining approval from city or state level IRBs or Privacy Boards may help optimize data collection. Uniformity of methods to adhere to regulatory requirements would ease the conduct of prehospital research.
Key words: Privacy rule; HIPAA; pediatric research; resuscitation research.

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INTRODUCTION

There are considerable barriers to conducting clinical studies in the prehospital setting, particularly when these studies involve children who have suffered cardiac arrest. When it is not possible to obtain prospective informed consent in studies with greater than minimal risk, federal regulations require that investigators seek an exception from informed consent,[1] a process that to date has not taken place for a pediatric study. Even for a purely observational study, there are substantial regulatory barriers. One relatively new addition to

these regulations is the Privacy Rule, which was enacted to prevent inappropriate distribution of protected health information. This rule has a compounded impact for prehospital research, because data typically must be collected from multiple emergency medical service (EMS) agencies and from multiple receiving hospitals.

The Privacy Rule was issued in December 2000 as a planned follow-up to the Health Insurance Portability and Accountability Act (HIPAA), issued in 1996. While the HIPAA regulations were enacted primarily to ensure that employees be able to change jobs without losing health insurance coverage, the Privacy Rule was enacted to protect the privacy of health information. The Privacy Rule tightly regulates the distribution of protected health information, an 18-item list of information that could potentially identify an individual. Specific authorization from the individual is generally necessary prior to disclosure of this information. When it is not feasible to obtain authorization to release protected health information for research purposes, a privacy board or institutional review board (IRB) may waive the authorization requirement if specific criteria are met.[2] The potential impact of the Privacy Rule on clinical research has been discussed,[3–6] and some investigators report that the Privacy Rule may negatively impact the conduct of clinical research[7–11] The impact of the Privacy Rule on observational research in the prehospital setting has not been described.

Investigators conducting prehospital research generally seek data from both EMS providers and from the hospitals to which patients are transported. EMS records may be used to identify patients with a given condition and the prehospital therapy they received. Outcome data are obtained from receiving hospitals. The Privacy Rule impacts the data collection process from both EMS systems and from receiving hospitals.

In response to the need for evidence-based methods to improve outcome from pediatric cardiac arrest, the CanAm Pediatric Cardiopulmonary Arrest Study Group was formed. The mission of this NIH-funded consortium of emergency medicine physicians, pediatricians, and intensivists is to establish evidence-based strategies to improve the outcome of children who suffer cardiac arrest outside the hospital As a first step in planning a methodologically robust interventional study, the group conducted a large, multicentered, observational study establishing the outcome of pediatric cardiac arrest patients managed by EMS providers in multiple systems across Canada and the United States. This initial study has reconfirmed the largely dismal outcome of pediatric cardiac arrest and has emphasized the need for clinical studies with complete outcome data.[12,13]

This report describes the impact of the Privacy Rule on the conduct of a multicentered, minimal risk, observational study involving children who suffered an out-of-hospital cardiac arrest. We analyzed the various strategies used in the CanAm study to collect data from both EMS and receiving hospitals to determine optimal strategies for conducting future research. While the Privacy Rule is an American regulation that does not apply in Canada, compliance with it is mandatory for Canadian organizations that deal with health care organizations in the United States.

METHODS

Study Design and Population

Following completion of a multicentered observational study establishing the outcome of pediatric cardiac arrest patients, the data collection experiences of investigators at each of seven participating CanAm study sites were elicited through study group telephone conference calls, via electronic surveys, and by follow-up communications (telephone and electronic mail). Principal investigators at each site (n = 7) completed a survey that included: the process by which they collected data, the size of their catchment area, the number of EMS agencies involved in the study at their site, the number of receiving hospitals, and the number of local IRBs that reviewed the study. Investigators were also asked in the survey to describe problems encountered in obtaining data both from EMS agencies and from receiving hospitals and to describe strategies used to overcome these problems. Detailed information from each EMS agency involved was not collected. The electronically distributed survey was designed collaboratively, with input from CanAm investigators, who are also authors on this publication. The results were compiled by an investigator with specific training in survey research.

Data Analysis

Qualitative information provided included a written narrative of the processes used to obtain approval for acquisition of patient-specific data. Qualitative data analysis was conducted by using the NVivo Qualitative Data Analysis Software (QSR International Doncaster, Australia). Quantitative data were collected on a structured data form; summary statistics are presented.

RESULTS

Complete data were provided from seven of the seven study sites. All seven sites reported successful IRB approval and success obtaining a waiver of HIPAA authorization from the primary academic institution.

Obtaining Data from EMS Providers

In three of the seven study sites, there was only one EMS agency involved in emergency responses. The

TABLE 1. Characteristics of Individual Study Sites

Site	Number of EMS agencies	Number of receiving hospitals	Number of IRBs involved	How were hospital survival data obtained	Approvals by state or local regulatory agencies
A	2	31	1	In-hospital personnel at the receiving hospitals provided survival data to the EMS director	None reported
B	1	28	"Multiple"	Emergency physicians at receiving hospitals	State Department of Health, City Privacy Officer
C	6	20	1	Data already collected for QA database	None reported
D	1	10	2	At the primary hospital, through medical records. For the other receiving hospitals, through the coroner's office.	Formal data-sharing agreement with coroner's office
E	1	1	1	In-hospital personnel at the one regional hospital to which all children who survived to hospital admission were transferred.	None reported
F	18	11	1	Data already collected for QA database	None reported
G	37	90	3	Data already collected for QA database. Outcomes confirmed via Vital Statistics records and the Social Security Death Index	Fire Commissioner, State Commissioner of Health, and approval by legal department of Health and Hospitals Corporation

other three centers had 2, 6, 18, and 37 participating EMS agencies (Table 1). The processes required to obtain approval to use data from EMS records in the study differed from site to site. Specific concerns raised by EMS systems included potential liability (concerns about who has access to the data and whether the data are discoverable), how patient confidentiality would be maintained, and the amount of work required, and therefore cost, for EMS employees to access the data. Some EMS systems sought approval at a state or city level to release information to researchers. In some cases, access to the records was readily available, as a study investigator worked within the EMS system. In other cases, approval was sought (and granted) from a Department of Health IRB or from a Fire Commissioner or Commissioner of Health.

In one U.S. city in which the city fire department operates the EMS system, obtaining permission to release EMS records to researchers required approval from the city Privacy Officer and a Data Use Agreement between the site investigator's institution and the city. Complete de-identification of the data, involving removal of all 18 patient identifiers stipulated by the Privacy Rule, was required prior to releasing them to investigators.[14] One EMS agency did not participate in the study in part because of the time-consuming nature of complying with the Privacy Rule and the lack of a clearly defined mechanism for compliance in the EMS setting.

Obtaining Data from Receiving Hospitals

The median number of receiving hospitals per study site was 20 (range of 1–90). In four sites, the study was submitted to and approved by one institutional review board (United States) or research ethics board (REB; Canada), whereas in three sites, it was submitted to two or more IRB/REBs. IRB/REB approval for the study was granted at each site investigator's primary institution. In all cases, the study was determined to pose minimal risk, and a waiver of informed consent was granted.

Specific approaches to the Privacy Rule varied between study sites. At each site, a study investigator was on faculty at one of the major receiving hospitals. IRB/REB approval was granted at each of these principal institutions with a waiver of HIPAA authorization, making the collection of outcome data from these principal institutions straightforward. Data sought from receiving hospitals included survival to hospital admission, survival to 24 hours, and survival to hospital discharge. At some sites, follow-up data were already being collected as part of a database independent of the study or as part of an ongoing quality assurance process, thus simplifying data collection. At these sites, the IRB/REB approved the use of these data for research purposes. At one site, out-of-hospital cardiac arrest has been designated as a public health issue by the state Department of Health. As such, the statewide registry of out-of-hospital cardiac arrests is not covered under the Privacy Rule. The investigators nonetheless attempted to operate in a Privacy Rule compliant fashion.

For sites with multiple receiving hospitals and no preexisting outcome database, obtaining follow-up information became problematic, requiring multiple mailings and phone calls to receiving hospitals. The manner in which receiving institutions complied with the Privacy Rule varied substantially. The Privacy Rule states that only one site need grant a waiver of HIPAA

authorization, but it is unclear what type of documentation is required. Some institutions released outcome data following verbal assurance that a waiver of HIPAA authorization had been granted at the principal institution, whereas others required submission to and review by the hospital privacy board. At one Canadian site, a data-sharing agreement was agreed upon with the provincial coroner's office and with the Ottawa Health Research Institute to obtain survival outcome. In other institutions, when attempts to obtain follow-up information from receiving hospitals were not productive, survival data were sought through city and state vital statistics records, the Social Security Death Index, and even through Internet search engines or print media. As was the case with collection of data from EMS agencies, support from governmental agencies (e.g., Health Commissioner) was sometimes helpful in assuring receiving hospitals that the sharing of information was appropriate.

DISCUSSION

Obtaining complete and accurate data in an efficient manner is vital to the success of a prehospital clinical study. Incomplete participation (e.g., if particular hospitals do not provide outcome data) can lead to bias that may invalidate study results.[11] Meaningful prehospital research depends on complete data from both EMS and receiving hospitals. The experience of the CanAm Study illuminates some of the regulatory hurdles that prehospital researchers may encounter and suggests processes to streamline the collection of complete research data. Successful strategies for obtaining prehospital and hospital information are summarized in Table 2.

Obtaining Data from EMS Systems

Obtaining data from EMS providers and agencies involved in noninterventional studies conducted in the prehospital setting may be challenging. Because most EMS agencies do not have a research review and approval process equivalent to an IRB or REB, there is no systematic approval mechanism for the use of EMS records for research purposes. Establishing an ongoing relationship between EMS agencies and IRB/REBs (through academic or governmental institutions, depending on local circumstances) is an important initial step in advancing EMS research. While obtaining IRB approval for a proposed project is an important and mandatory initial step, this does not guarantee that EMS agencies will provide the desired data. Obtaining approval of the study from local or regional government officials or regulatory agencies may enhance the credibility of the investigators and increase the likelihood of success. CanAm investigators who sought approval from state or city government officials or agencies were consistently successful and found such approval helpful in obtaining data. Potentially helpful sources of governmental approval at the state or city level include HIPAA offices, health departments, and Fire Department commissioners (in cities with Fire Department-based EMS systems).

Obtaining Outcome Data from Receiving Hospitals

For the CanAm study, only limited follow-up information was requested from receiving hospitals (survival to hospital admission, survival to 24 hours, and survival to hospital discharge). However, in prehospital

TABLE 2. Summary of Successful Strategies Used by CanAm Investigators in Seeking Data from EMS Agencies and Receiving Hospitals.

Obtaining prehospital data	Obtaining follow-up data from receiving hospitals
• Seek approval from the appropriate academic or governmental institutional review board. • Seek a waiver of HIPAA authorization from the appropriate academic or governmental Privacy Board or HIPAA office. • Seek approval from agencies within which the involved EMS agencies operate, such as the department of health or the fire department. • Forward such approvals to the director of each involved EMS agency. • Provide reimbursement to EMS agencies if their personnel will be asked to extract data for research purposes. • For studies involving few EMS agencies, involving EMS personnel from each agency in the study design may increase buy-in and facilitate data collection.	• Seek approval from the appropriate institutional review board and a waiver of HIPAA authorization from the appropriate Privacy Board or HIPAA office. • Consider seeking approval from a state or regional review board or HIPAA office in order to increase acceptability by receiving hospitals. • Forward such approval to the IRB and Privacy Board/HIPAA office at receiving hospitals from which follow-up data will be requested. (Investigators may want to include a copy of the section of the Privacy Rule indicating that individual institutions are not required to independently review requests for a waiver of HIPAA authorization if such a waiver has been granted by another qualified institution.) • Attempt to identify an individual within each receiving hospital who can oversee the IRB/HIPAA process and upon approval, who can extract and forward study data. • For studies in which follow-up is limited to survival, consider the use of vital statistics records, the Social Security Death Index, print media, or internet search engines

interventional studies, obtaining more detailed hospital information will likely be desirable. Some of the processes used by investigators in the CanAm study may be particularly useful in encouraging complete and accurate data transmission from receiving hospitals. Several investigators were able to collect hospital outcome data from databases created for quality assurance purposes. In studies for which outcome data are limited to survival, this is likely to be an effective strategy when available. If such data are de-identified before being transmitted to researchers, there is no need to obtain HIPAA authorization or a waiver of such authorization.

In some cases, outcome data were not available through a preexisting database and needed to be accessed directly from receiving hospitals. The Privacy Rule requires that institutions have documentation of a waiver of HIPAA authorization before releasing any protected health information to researchers. The Privacy Board or Privacy Officer at each institution need not independently determine eligibility for a waiver; documentation that a waiver was granted at one participating institution is sufficient. However, the Privacy Board at each individual institution may choose to review a protocol independently.[15] CanAm investigators encountered differing requirements from the various receiving hospitals. In part, this may have been due to the hospitals' various risk management concerns and in part because of differing interpretations or application of the Privacy Rule. Because there was often no uniform approach to obtaining outcome data from receiving hospitals, this process became very labor-intensive and at times unsuccessful. One strategy that may facilitate this process is to seek approval from a regional health care council, local hospital association, medical association, or city or state IRB or Privacy Board. Approval from one of these agencies may carry more weight with receiving hospitals than approval from the IRB at another hospital.

When only limited follow-up information is necessary and a study involves multiple receiving hospitals, the use of state or city vital statistics records or the Social Security Death Index may be a useful adjunct to seeking data from each receiving hospital. Patient-specific follow-up information may be obtained by submitting a protocol to a state IRB and obtaining outcome data from the state vital statistics registry using death notices and ICD-9 discharge codes. However, the vital statistic records will not capture patients who die after being transferred outside of geographic limits, and the Social Security Death Index will not capture those who are not enrolled in Social Security. If missing data systematically overrepresent either survivors or nonsurvivors, they have the potential to bias the results of a study. Ensuring access to follow-up data is an important component of good prehospital resuscitation research.

CONCLUSIONS

The mission of the CanAm Pediatric Cardiopulmonary Arrest Study Group is to establish evidence-based strategies to improve the outcome of children who suffer cardiac arrest outside the hospital. To accomplish this goal, complete prehospital and hospital data must be accessible by researchers. We found that the methods of accessing follow-up data from EMS agencies and receiving hospitals varied greatly from site to site, largely in response to local conditions. In sites with many EMS agencies and receiving hospitals, the difficulty of obtaining follow-up data is compounded. Obtaining approval from city or state level Privacy Boards or IRBs may ease some of the difficulty of obtaining follow-up data.

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